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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,011	02/17/2000	John Cooper Cox	017227/0155	6856

7590

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EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/10/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/506,011

Applicant(s)

COX ET AL.

Examiner

Shanon Foley

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

THE REPLY FILED 13 August 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 13 August 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

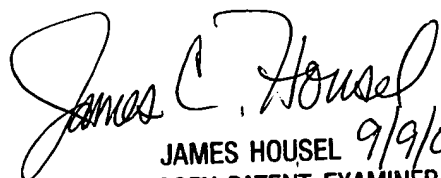
Claim(s) rejected: 1-43 and 52.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

Continuation of 2. NOTE: New consideration would be required under 112, second paragraph because there is a lack of antecedent basis for "said negatively charged organic complex" in claim 5.

Continuation of 5. does NOT place the application in condition for allowance because: It is maintained that Nakanishi et al. anticipates or renders the instant claims prima facie obvious because the reference teaches a negatively charged liposome complexed with an antigen, see Table 1 and Figure 1 on page 794. Applicant has provided the pI of the antigens taught by Nakanishi et al. and assumes that the liposome and the antigen and the MLV are co-dispersed at a certain pH. This assumption has no support and does not overcome the prior art rejection. It is maintained that antigens inherently possess some amino acids that are positively charged and that these positively charged residues are naturally attracted to negative charges by electrostatic association. Furthermore, the method of loading an antigen into a liposome is not a limitation in the claims. Applicant also asserts that Nakanishi et al. only teaches that the positively charged liposomes effectively bind to macrophages. In response, while the positively charged liposomes had a greater effect on murine macrophages, there is a slight CTL induction with the negatively charged liposomes, see Figure 1. Therefore, although the negatively charged liposomes do not demonstrate a profound effect on the macrophages, an induction of CTL, however slight, is still an induction. Applicant further asserts that a saponin is an adjuvant and a phospholipid is not, so the combination of Nakanishi et al. and Barr et al. is improper because the liposome of Nakanishi et al. is only a delivery vehicle and not used for immunostimulatory purposes. In response, it is agreed that Nakanishi et al. uses liposomes to deliver antigens, see the materials and methods section and Table 1 on page 794. Nakanishi et al. also analyses the immune response elicited by each variously charged liposome. Therefore, the liposome compositions of Nakanishi et al. are also adjuvants, even though some of the complexes induce a greater immune response due to a difference in charge. Also, the request for reconsideration does not obviate the double patenting or the rejection under 112, first paragraph.



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